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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,225	03/26/2001	Peter Hawkins	109068	5800

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EXAMINER
DO, PENSEE T

ART UNIT	PAPER NUMBER
1641	12

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/816,225	Applicant(s) PETER HAWKINS	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears n the cover she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Applicati n Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group 2 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that group I drawn to a method of determining a number of magnetic particles is sufficiently similarly related to group II comprising a method of performing a binding assay by determining the number of magnetic particles both of which are performed by determining the difference in a resonant frequency when a sample is selectively exposed to a magnetic field. This is not found persuasive because the method of group I does not involve an antibody-antigen reaction. The method of group I and group II also have different classifications and thus would require different searches. The search for group I is not required for group II. Applicants also traverses that all claims 1-26 are related and that a thorough search for the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. Again, the search for group I is not required for group II because the groups have distinct classifications. Such non-required search for the non-elected group would be a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and confusing because the preamle is inconsistent with the body of the claim. Part (d) determines the number of magnetic particles bound to the substrate, thus the preamble should be directed to the same sort of method of quantifying.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-11, 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) further in view of Rapoport (US 5,978,694).

Kritz teaches a method of detecting an analyte comprising the steps of providing a sample comprising a marker, a binder (recognition element), said marker having material comprising an externally, inductively detectable relative magnetic permeability constant of at least about 600, said recognition element binds to or competes for binding with the analyte, said marker and said recognition element induce in a transducer comprising a coil a first inductance value when said analyte is absent from said sample and a second inductance value when said analyte is present in said sample. The recognition element (binder) is immobilized to a matrix (substrate) – see

col. 6, lines 36-37. The sample containing the analyte and marker are added to the carrier. A competition or a sandwich reaction formed. The reaction was placed in a measuring coil and inductance changes noted. The inductance change in turn affected either the resonance frequency for an LC-circuit in which the coil was a part, or the balancing expressed as a voltage response, in a Maxwell bridge in the coil was a part. The relationship between the change of resonance frequency in Hz, or the voltage difference in mV, is a linear relationship against the number of particles in the measuring solution, expressed as iron concentration. The molecular layer (recognition element) being an antibody/antigen and the second molecules being antigens or antibodies. (see col. 3, line 10-col. 4, lines 47; col. 5, line 10-col. 6, line 42; col. 9, lines 1-4).

However, Kritz does not teach measuring the difference in resonant frequency when the substrate is exposed to a magnetic field and when the substrate is not exposed to the magnetic field; a solenoid coil.

Rapoport teaches a method for detecting in a sample a substance which responds to an applied magnetic field, such as paramagnetic substance. The sample is placed in an applied magnetic field, and the effect of the sample on a performance characteristic of a first electrical conductor is measured by the first measuring means and the value is displayed and/or optionally inputted to a data storage and analysis means. Subsequent measurements of this same performance characteristic of the first electrical conductor are made over time, either continuously or at pre-determined intervals. The performance characteristics are inductance, capacitance, etc. (See col. 3,

lines 35-37). It is also desirable to compare the effect of the sample on the conductor in the presence of the applied magnetic field with the effect of the sample on the conductor in the absence of the applied magnetic field. (see col. 3, lines 20-26). Rapaport teaches a solenoid coil (figure 1).

It would have been obvious to one of ordinary skills in the art to measure the performance characteristic such as inductance of the sample in the presence and absence of the applied magnetic field as taught in Rapaport in the method of Kritz because that way the two measurements can be compared, taking into consideration the calibrations necessary to account for the differences, if any, in the performance characteristic of the first and second conductors. The corrected difference between the two measurements is then a function solely of the presence of a substance in the sample which responds to the applied magnetic field.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) further in view of Rapoport (US 5,978,694) further in view of Houghton et al. (US 5,679,342).

Kritz and Rapoport have been discussed above.

However, Kritz and Rapoport fail to teach a plastic strip as the substrate.

Houghton et al. teaches an assay wherein the receptor layer is immobilized on a matrix/solid support such as plastic strips, microliter plates, or any surface onto which antigen may be immobilized.(See col. 19, lines 45-51).

It would have been obvious to one of ordinary skills in the art that using matrix/solid support such as plastic strips is well known in the art. Thus, one of ordinary

skills in the art would find it obvious to use plastic strips as taught by Houghton in the modified method of Kritz and Rapoport since Kritz suggested that the receptors are immobilized to a matrix and it is well known in the art that matrix for immobilizing receptor can be plastic strips for these plastic strips are polymers with compatible functional groups that immobilize the receptors securely on the strips and do not interfere with the molecular interaction of the receptor and the target analyte.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Pensee Do
Patent Examiner
October 21, 2002